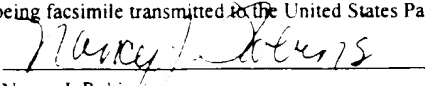


CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 4, 1996


Nancy J. Robins

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Lynn E. Spitler et al.

Serial No.: 08/288,057

Filing Date: 10 August 1994

For: PROSTATIC CANCER VACCINE

Examiner: P. Gambel

Group Art Unit: 1816

**DECLARATION OF JEAN CLAUDE BYSTRYN, MD
PURSUANT TO 37 C.F.R § 1.132**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Jean Claude Bystry, MD, declare as follows:

1. I am a member of the Department of Dermatology at the New York University Medical Center. A copy of my *Curriculum Vitae* is attached hereto as Exhibit A. I have no association or connection with Jenner Technologies, the assignee herein.

2. I have reviewed the Declaration Under 37 C.F.R. 1.132 prepared by Dr. Lynn E. Spitler describing the results of a clinical study directed to the use of prostate specific antigen (PSA) as an active ingredient in an antiprostata cancer vaccine. I am also familiar with the study itself, and with the results that were obtained.

3. The purpose of the study was to obtain evidence that the vaccines would raise a sufficient cellular immune response to have a beneficial effect with respect to prostate tumors. Such a result could be shown directly by measuring cytotoxic lymphocyte (CTL) generation, however, I am aware that this was not possible in these studies because the assay was not satisfactory because of the lack of an appropriate target cell for the assay.

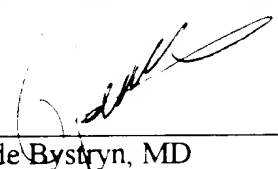
4. The responses measured are understood in the art to be satisfactory substitutes for measuring CTLs. Thus, the proliferation of lymphocytes from two of the patients in response to contact with PSA or in response to peptides representing putative PSA epitopes is indicative of an appropriate cellular immune response. The ability of PSA or PSA derived peptides to stimulate cytokine production -- i.e., gamma interferon and IL-4 production -- from lymphocytes in these patients also indicates that the cellular response is obtained specifically with respect to PSA. The observation of the development of a positive skin test response to PSA in one patient is also consistent with these observations showing the development of cell-mediated immunity in the patients.

5. In my opinion, the results obtained in this clinical study provide evidence that the vaccines are likely to be effective in exerting a beneficial effect on patients with prostate tumors or at risk for prostate tumors.

6. The efficacy shown for the vaccine tested in the foregoing clinical studies further provides evidence that analogous vaccines based on host tissue antigen, such as prostate specific membrane antigen (PSMA) and prostate acid phosphatase (PAP) would behave in a similar manner. It is also known that if the entire antigen is effective as a vaccine, portions of the antigen may be effective as well, especially if manipulated by art-known methods to enhance their immunogenicity, such as by coupling them to carrier.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

October 10, 1996



Jean Claude Bystryn, MD

CURRICULUM VITAE

10/30/86

JEAN-CLAUDE BYSTRYN, M.D.

DATE OF BIRTH: May 8, 1938

PLACE OF BIRTH: Paris, France (U.S. Citizen)

EDUCATION:

- 1958 B.S. University of Chicago (biochemistry), Special honors in the natural sciences
1962 M.D. New York University School of Medicine, New York, NY

POST-GRADUATE TRAINING:

- 1962-1963 Intern (mixed), Montefiore Hospital, New York, NY
1963-1964 Residency (medicine), Montefiore Hospital, New York, NY
1966-1969 Residency (dermatology), NYU School of Medicine, New York, NY
1968-1969 USPH post-doctoral research fellow (vascular physiology), Laboratory of Dr. Chester Hyman, Dept. of Physiology and Dermatology, University of Southern California, Los Angeles, CA
1969-1972 USPH post-doctoral research fellow (immunology), Laboratory of Dr. Jonathan Uhr, Dept. of Medicine, NYU School of Medicine, New York, NY

MEDICAL LICENSURE:

- 1963 State of New York
1964 State of California

BOARD CERTIFICATION:

- 1970 American Board of Dermatology
1986 American Board of Immunodermatopathology

MILITARY EXPERIENCE:

- 1964-1966 USPHS Heart Disease Control Officer, Albany, NY

HOSPITAL AND TEACHING APPOINTMENTS:

- 1969- Assistant Visiting Dermatologist, Bellevue Hospital Center, New York
1969- Assistant Attending, University Hospital, NYU School of Medicine, New York
1970-1971 Instructor, Dept. of Dermatology, NYU School of Medicine, New York
1970-1997 Associate Attending, Depts. of Dermatology and Syphilology, Bellevue Hospital Center, New York
1971-1972 Assistant Professor of Clinical Dermatology, Dept. of Dermatology, NYU School of Medicine, New York
1972-1976 Assistant Professor, Dept. of Dermatology, NYU School of Medicine, New York
1972- Director, Immunofluorescence Laboratory, Dept. of Dermatology, NYU School of Medicine, New York
1974- Co-Director, Bullous Disease Clinic, Skin and Cancer Unit, NYU School of Medicine, New York
1976-1984 Associate Professor, Dept. of Dermatology, NYU School of Medicine, New York
1982- Director, Melanoma Immunotherapy Clinic, Skin and Cancer Unit, NYU Medical Center, New York
1983-1992 Executive Committee, Kaplan Cancer Center, NYU Medical Center, New York
1983- Director, Melanoma Program, Kaplan Cancer Center, NYU Medical Center, New York
1984- Professor, Dept. of Dermatology, NYU School of Medicine, New York

Exhibit A

BYSTRYN, JEAN-CLAUDE
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HONORS AND AWARDS:

- 1964 Ford Foundation Fellowship for early entrance to college
- 1968 Husik Prize in Dermatology, NYU School of Medicine
- 1979 Irma T. Hirsch Career Scientist Award
- 1985 Skin Cancer Foundation Annual Award
- 1987 Philippine Society of Dermatology, Honorary Member
- 1990 AOA
- 1990 Society Francaise de Dermatologie, Honorary Member
- 1991 The Hellenic Society of Dermatology, Honorary Member

CHAIRMAN OF SYMPOSIA/WORKSHOPS AT NATIONAL AND INTERNATIONAL CONFERENCES:

- 1982 Int'l Symposium on Stratum Corneum, Cardiff
- 1982 Fifth Southeast Asian Conference on Dermatology, Manila
- 1982 XVIth Int'l Congress on Dermatology, Tokyo
- 1983 Joint Annual Meeting of the Society of Investigative Dermatology and European Society for Dermatologic Research, Washington, DC
- 1983 First World Congress on Cancers of the Skin, New York
- 1983 XIIth Int'l Pigment Cell Conference
- 1985 Second World Congress on Cancer of the Skin, New York
- 1985 Joint International Meeting of the SID and JCID, Washington, DC
- 1987 XVIth International Congress of Dermatology, Berlin
- 1989 Second International Conference on Melanoma, Venice
- 1990 NIH Research Workshop on Alopecia Areata, Organizer
- 1992 XVIIth International Congress of Dermatology, New York
- 1993 Third International Conference on Melanoma, Venice
- 1993 New York Academy of Sciences Conference on "Specific Immunotherapy of Cancer with Vaccines," Washington, D.C., Conference Chair
- 1994 International Symposium "Skin Therapy Update '94," Crete, Co-Chairman
- 1995 Sixth World Congress of Cancers of the Skin, Buenos Aires, Chairperson of Plenary Session on Basic Science
- 1996 International Conference for Apheresis 1996, Kyoto, Chair

PROFESSIONAL SOCIETIES:

- Society Francaise de Dermatologie, Honorary Member
- Philippine Society of Dermatology, Honorary Member
- American Academy of Dermatology
- American Dermatological Association
- American Association of Immunologists
- American Association for Cancer Research
- Society for Investigative Dermatology
- American Society for Cell Biology
- International Society for Tropical Dermatology
- American Federation for Clinical Research
- New York Dermatological Society
- Dermatology Foundation
- International Pigment Cell Society
- PANAMERICAN Society for Pigment Cell Research
- International Society for Vaccines
- Clinical Immunology Society
- Society for Biological Therapy

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ASSIGNMENTS IN PROFESSIONAL SOCIETIES OR MEDICAL JOURNALS:

- 1975-1978 Mycosis Fungoides Cooperative Group, Chairman, Immunotherapy Panel
- 1980-1982 Dystrophic Epidermolysis Bullosa Foundation, Board of Medical Advisors
- 1980- Skin Cancer Foundation, Board of Medical Advisors and Chairman Grant Review Committee
- 1981-1980 American Academy of Dermatology, Task Force on Immunopathology
- 1986-1987 New York Dermatological Society, Secretary
- 1987-1988 New York Dermatological Society, President
- 1983- National Alopecia Areata Foundation, Medical Advisory Board
- 1987- Molecular Therapeutic, Editorial Board
- 1990- Vaccine Research, Editorial Board
- 1992-1996 Journal of the European Academy of Dermatology and Venereology, Editorial Board
- 1993- Society for Investigative Dermatology, Committee for Industrial Sponsorship
- 1993- American Dermatological Association, Membership Committee
- 1993- National Vitiligo Foundation, Medical Advisory Board
- 1994- American Academy of Dermatology, Commission on Melanoma
- 1994- American Board of Dermatology, Training Program in Clinical and Laboratory Dermatological Immunology Review Committee
- 1994- American Board of Dermatology, Recertification Committee
- 1995- American Skin Association, Medical/Scientific/Policy Advisory Committee
- 1996 NIH Ad Hoc Reviewer, Biological Response Modifier Program
- 1996-2000 American Academy of Dermatology, Manpower Committee

PUBLICATIONS

1. BYSTRYN J-C, HYMAN C. Skin blood flow in atopic dermatitis. *J Invest Derm* 52:189, 1969.
2. BYSTRYN J-C, FREEDMAN RI, HYMAN C. Clearance of iodoantipyrene from Mecholyl blanched skin in atopics. *Arch Derm* 100:165, 1969.
3. LEVAN NE, BYSTRYN J-C, HYMAN C. Temperature and blood flow in macules of lepromatous leprosy. *Int J Leprosy* 37:249, 1969.
4. BYSTRYN J-C, GRAF MW, UHR JW. Regulation of antibody formation by serum antibody. II. Removal of specific antibody by means of exchange transfusion. *J Exp Med* 132:1279, 1970.
5. UHR JW, BYSTRYN J-C, GRAF MW. The regulation of antibody formation. In: Morphological and Fundamental Aspects of Immunity, ed. by Lindahl-Kiessling, Alm and Hanna; Plenum Press, New York, 1971, pp 395.
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7. SCHENKEIN I, BYSTRYN J-C, UHR JW. Specific removal of in vivo antibody by extracorporeal circulation of an immunoabsorbent in gel. *J Clin Invest* 50:1884, 1971.
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9. BYSTRYN J-C. Drug fever. Am J Med Science 264:467, 1972.
10. BYSTRYN J-C, BART RS, LIVINGSTON P, KOPF AW. Immunity to murine melanoma. *J Invest Derm* 60:249, 1973.
11. BYSTRYN J-C, SISKIND GW, UHR JW. Binding of antigen by immunocytes 1. Effect of ligand valency on binding affinity of MOPC 315 cells for DNP-conjugates. *J Exp Med* 137:301, 1973.

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14. BYSTRYN J-C, SCHENKEIN I, UHR JW. Double antibody radioimmunoassay for tumor antibodies. J Natl Cancer Inst 52:911-915, 1974.
15. BYSTRYN J-C, SCHENKEIN I, BAURS, UHR JW. Partial isolation and characterization of antigen(s) associated with murine melanoma. J Natl Cancer Inst 52:1263-1269, 1974.
16. BYSTRYN J-C, BART RS, LIVINGSTON P, KOPF AW. Growth and immunogenicity of B16 murine melanoma. J Invest Derm 63:369-373, 1974.
17. BYSTRYN J-C, ABEL E, DEFEO C. Pemphigus foliaceus: subcorneal intercellular antibodies of unique specificity. Arch Derm 110:857-862, 1974.
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55. **BYSTRYN J-C, JACOBSEN JS, LIU P, HEANEY-KIERAS J.** Comparison of cell-surface human melanoma-associated antigens identified by rabbit and murine antibodies. *Hybridoma* 1:465-472, 1982.
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57. **ZHU X-J, BYSTRYN J-C.** Heterogeneity of pemphigoid antigens. *J Invest Derm* 80:16-20, 1983.
58. **BYSTRYN J-C.** Natural stratum corneum antibodies and antigens. In: Stratum Corneum, ed. by R Marks and G Plewig; Springer-Verlag, Berlin, pp 112-128, 1983.
59. **NAUGHTON GK, EISINGER M, BYSTRYN J-C.** Antibodies to normal human melanocytes in vitiligo. *J Exp Med* 158:246-251, 1983.
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61. **MEDINA AL, ROBBINS TD, BYSTRYN J-C., ACKERMAN AB.** Limitations in the diagnosis of vesiculo-bullous diseases. *Am J Dermatopath* 5(1):7-11, 1983.
62. **NAUGHTON GK, EISINGER M, BYSTRYN J-C.** Detection of antibodies to melanocytes in vitiligo by specific immunoprecipitation. *J Invest Derm* 81:540-542, 1983.
63. **GOLDBERG D, SABOLINSKI M, BYSTRYN J-C.** Regional variations in the expression of bullous pemphigoid antigen in human skin. *J Invest Derm* 82:326-328, 1984.
64. **JOHNSTON D, BYSTRYN J-C.** Mechanism of autodegradation of cell surface macromolecules shed by human melanoma cells. *Exp Cell Res* 152:179-187, 1984.
65. **BYSTRYN J-C.** Adjuvant therapy of pemphigus. *Arch Derm* 120:941-951, 1984.
66. **ZHU X-J, EISINGER M, BYSTRYN J-C.** Differentiation and shedding of surface macromolecules of human keratinocytes. *J Invest Derm* 83:340-343, 1984.
67. **NAUGHTON GK, LIPKIN G, BYSTRYN J-C.** Expression of vitiligo antigen on a revertant line of hamster melanoma cells. *J Invest Derm* 83:317-319, 1984.
68. **BYSTRYN J-C.** Immunology and immunotherapy of human malignant melanoma. *Dermatologic Clinics* 3:327-334, 1985.
69. **JOHNSTON D, BYSTRYN J-C.** Effect of tunicamycin on release of macromolecules and tumor antigens by human melanoma cells. *Cancer Res* 45:1772-1777, 1985.
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72. **BYSTRYN J-C, BERNSTEIN P, LIU P, VALENTINE F.** Immunophenotype of human melanoma cells in different metastases. *Cancer Res* 45:5603-5607, 1985.
73. **LIPKIN G, NAUGHTON GK, ROSENBERG M, BYSTRYN J-C.** Vitiligo-related pigment cell differentiation antigens are expressed on malignant melanoma cells following phenotypic reversion induced by contact inhibitory factor. *Differentiation* 30:35-39, 1985.
74. **BYSTRYN J-C.** Interpretation of immunofluorescence tests in dermatology. *Progress in Dermatology* 19:1-8, 1985.
75. **BYSTRYN J-C, VALENTINE F, BERNSTEIN P.** Tumor antigen heterogeneity and the specific immunotherapy of melanoma. In: Biological Molecular and clinical Aspects of Pigmentation, ed. by J Bagnana, SW Klaus, E Paul and M Schantl; Univ. of Tokyo Press, Tokyo, pp 391-396, 1985.
76. **HEANEY-KIERAS J, BYSTRYN J-C.** Identification and purification of 115kd and 125kd cell-surface human melanoma-associated antigens. *J Nat Cancer Inst* 77:643-646, 1986.
77. **NAUGHTON GK, MAHAFFEY M, BYSTRYN J-C.** Antibodies to surface antigens of pigmented cells in animals with vitiligo. *Proc Soc Exp Biol and Med* 181:423-426, 1986.
78. **SISON-FONACIER L, BYSTRYN J-C.** Regional variations in antigenic properties of skin: A possible cause for disease-specific distribution of skin lesions. *J Exp Med* 164:2125-2130, 1986.
79. **BYSTRYN J-C, JACOBSEN S, HARRIS M, ROSES D, SPEYER J, LEVIN M.** Preparation and characterization of a polyvalent human melanoma antigen vaccine. *J Biol Resp Modif* 5:211-224, 1986.
80. **NAUGHTON GK, REGGIARDO D, BYSTRYN J-C.** Correlation between vitiligo antibodies and extent of depigmentation in vitiligo. *J Am Acad Derm* 15:978-981, 1986.
81. **BYSTRYN J-C, SABOLINSKI M.** Effect of substrate on indirect immunofluorescence tests for intercellular and basement membrane zone antibodies. *J Am Acad Derm* 15:973-977, 1986.
82. **BYSTRYN J-C, KOLKS-NAUGHTON G, LIPKIN G.** Vitiligo antigens: Relation to pigment cell differentiation and melanoma. In: Cutaneous Melanoma Status of Knowledge and Future Perspective, ed. by U Veronesi, N Cascinelli, M Santinami; Academic Press, London pp 191-197, 1987.
83. **JOHNSTON DJ, SCHACHNE J, BYSTRYN J-C.** Identification of immunogenic B16 melanoma-associated antigens. *J Biol Resp Modif* 6:108-120, 1987.
84. **BYSTRYN J-C, RIGEL D, FRIEDMAN RJ, KOPF A.** The prognostic significance of hypopigmentation in malignant melanoma. *Arch of Derm* 123:1053-1055, 1987.
85. **SISON-FONACIER L, BYSTRYN J-C.** Heterogenicity of pemphigus vulgaris antigens. *Arch Derm* 123:1507-1510, 1987.
86. **SABOLINSKI ML, BEUTNER EH, KRASNY S, KUMAR V, HUANG J, CHORZELSKI TP, SAMPAIO S, BYSTRYN J-C.** Substrate specificity of anti-epithelial antibodies of pemphigus vulgaris and pemphigus foliaceus sera in immunofluorescence tests on monkey and guinea pig esophagus sections. *J Invest Derm* 88:545-9, 1987.
87. **LIPKIN G, NAUGHTON GK, ROSENBERG M, BYSTRYN J-C.** Reversion of the malignant melanoma phenotype with induction of pigment cell differentiation antigens and in vitro growth control by a contact inhibitory factor.
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